Click® Portal for Clinical Trials 3.1 (CTMS)

RESEARCH STUDY COORDINATOR GUIDE
BARBARA SUMMERS, SYSTEMS CONSULTANT
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Participant Workflow

Add Participant → Schedule Anticipated Consenting Visit (if built in) → Consent Participant → Schedule Screening Visit(s)

Log Screening Visit(s) Complete → Register Participant → Schedule Study Visit(s) → Log Study Visit(s) Complete
Logging In

I. Logging In – Internal Access

a. Staging Site: http://phx04521.bhs.bannerhealth.com/Banner-Staging-Store/

<table>
<thead>
<tr>
<th>Test Function</th>
<th>Login</th>
<th>Password</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory</td>
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</tr>
<tr>
<td>Budget Specialist</td>
<td>bs</td>
<td>1234</td>
</tr>
<tr>
<td>Budget Director</td>
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<td>1234</td>
</tr>
<tr>
<td>CTSM/Research Director</td>
<td>ctsm</td>
<td>1234</td>
</tr>
<tr>
<td>Principal Investigator</td>
<td>pi</td>
<td>1234</td>
</tr>
<tr>
<td>Invoicing Specialist</td>
<td>is</td>
<td>1234</td>
</tr>
<tr>
<td>Financial Director</td>
<td>fd</td>
<td>1234</td>
</tr>
<tr>
<td>Study Coordinator</td>
<td>sc</td>
<td>1234</td>
</tr>
<tr>
<td>Study Coordinator</td>
<td>coord</td>
<td>1234</td>
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<tr>
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<td>1234</td>
</tr>
<tr>
<td>Contract Management Specialist</td>
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<td>1234</td>
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<td>1234</td>
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<tr>
<td>Department Reviewer</td>
<td>dept</td>
<td>1234</td>
</tr>
<tr>
<td>Legal Department</td>
<td>legaldept</td>
<td>1234</td>
</tr>
</tbody>
</table>

b. Production Site: http://phx07535.bhs.bannerhealth.com/Banner-Prod-Store/

User Name is your Banner LAN ID.
Password is your Banner LAN password.
II. **Logging In – External Access**

   b. Click on option.

   c. Login to Huron Click® Portal.

   - **User Name** is your Active Directory Username.
   - **Password** is your Active Directory password.
My Inbox
Once you log in, you are taken to your Inbox workspace (My Inbox), which lists the items that need your attention.

Navigating Click® CTMS
III. Locate Study.
   a. From My Inbox, click CTMS.

   ![Banner Health CTMS Interface]
   
   b. Locate study on list and click Study Name. You will only see studies in the list where you are listed as part of the Study Staff or the assigned Research Study Coordinator. You can only add participants and log visits on studies that are listed as Active.

   ![List of Studies]

   c. You are now in the Study Summary.
Participant Workflow

I. **Add Participant to Study.**
   a. Click “Add Participant” to begin a new enrollment.

   ![Add Participant Image]

   b. Fill in the Participant Information. Fields denoted by a red asterisk (*) are required.

   ![Participant Information Image]

   c. Click “Continue.”

   d. Fill in the Participant Contact Information. You might not have much information about a new participant at this point, so only the fields denoted by a red asterisk (*) are required. You can edit the participant later to add in any missing information.
1. **Preferred E-mail Address:** Enter the participant’s e-mail address if available.

2. **Address:** Enter the participant’s home address and mailing address. If the mailing address is the same as the home address, check the (Same As Home Address) box and it will auto-populate.

3. **Primary Phone Number:** Enter the participant’s primary contact phone number.

4. **Business Phone Number:**

5. **Secondary Phone Number:**

6. **Participant’s personal physicians for notification:** Click “Add” to add participant’s primary care physician or referring physician. The Physician Data pop-up will appear. Complete as much information as possible about the physician and hit “OK.” To add multiple physicians, click “OK and Add Another.”
7. **Contacts**: This is where you will add any additional contacts. Click “Add” to add participant’s contacts information. The Contact pop-up will appear. Fields denoted by a red asterisk (*) are required. The Contact Priority field (Question #2) is numeric. Please enter 1, 2, 3 and so on for contact priority. Click “OK” when done, or “OK and Add Another” to enter multiple contacts.
Contact

Enter or update the contact details below.

1. *What is the contact’s relationship to the subject?
   - Advocate
   - Aunt/Uncle
   - Employer
   - Grandparent
   - Guardian
   - Other
   - Parent
   - Self
   - Significant Other/Partner
   - Son/daughter
   - Spouse
   - Study Partner
   If Other, please specify:

2. *In what priority should the person be contacted?

3. *Is this an emergency contact?:
   - Yes
   - No

4. Honorable:

5. *First Name:

   Middle Name:

   * Last Name:

   Suffix:

6. Same as Participant: □

   * Address 1:

   Address 2:

   Address 3:

   * City:

   * State:
     -- Select One --

   * ZIP/Postal Code:

7. *Phone:

8. Mobile

9. E-mail:

* Required
8. **Referring Physician:** Click “Add” to add a referring physician. The Add Referring Physician pop-up will appear. Click “Select” to search for a physician by name in the CTMS database and select the physician from the list. If a physician has referred a patient from outside our network, the user will enter the name in the box under **If Other, please specify the physician Name:**, which is a free text field. If there is no referring physician, leave both fields blank, which indicates there is not a referring physician.

9. **Referral Source:** Select the appropriate referral source from the drop-down.

- Click “Continue.”
- Fill in the Participant Profile. Fields denoted by a red asterisk (*) are required.
1. **Is the participant’s primary language English?** Select yes or no. If unknown, select “No,” and move to the next question.

2. **If no, please specify a language:** Select the participant’s language from the drop-down menu. If the language is Unknown, select “Unknown” here. If the language is not listed, select “Other” and a field will populate under the question “a.** If Other, please enter here:** This is a free text field, and you can type in the language that is not listed.

3. **Ethnicity:** Select the participant’s ethnicity from the list. If unknown, select Unknown.

4. **Race:** Select the participant’s race from the list. If unknown, select Unknown.

   g. Click “Continue.”

   h. The participant is now added to the study and is in “Pre-Screening.”

II. **Anticipated Consent (OPTIONAL Workflow).**

   The Anticipated Consent workflow allows the Study Coordinator to add a new potential participant to a study and create the initial visit at which consent will take place. This workflow is optional and in building a new study, staff will need to indicate whether or not an anticipated consent date is required for participants in the study.

   a. Click “Schedule Consenting Visit” under **Next Steps.**

   b. The “Schedule Consenting Visit” pop-up will appear. Select Visit Date and Time and add consenting visit comments.
c. Log Anticipated Consenting Visit complete. Click “Log Visit Complete.”

d. Complete Anticipated Consent Visit screen.
1. **Actual Visit Date:**
2. **Study Coordinator:**
3. * Visit Notes:
4. * Is this visit complete?
5. * Has the participant been consented?
   a) * Consent Information: Click “Add” under Consent Information to upload original consent.
      1. Consent Date: Enter date of original consent.
      2. Select Consent Type and Name.
      3. File Name: Enter File Name as “Consent Type_Approved_YEAR-MONTH-DAY.” EXAMPLE: “Main consent_approved 2016-NOV-30”. If there is not an approval date of the consent, enter the name of the consent and the version number.
      4. Choose File to select consent form for upload.
      5. Consent Notes: Enter consenting notes for participant. The consent notes should be specific to the consent process. This should be the same as the template consent notes and include important details related to the consent process.
6. * Did the participant agree to be re-contacted in the future for additional research opportunities? If the participant signed the consent for additional research opportunity contact, select Yes and complete the questions. If not, then select No.

### III. Consent Participant.

a. Click “Consent Participant” under **Next Steps**.

b. The “Consent Participant” pop-up will appear.

c. Click “Add” under Consent Information to upload the participant’s original consent. The Consent Forms pop-up will appear.
1. **Consent Date**: Enter date of original consent.
2. **Select Consent Type and Name**: Select consent type from the drop-down menu.
3. **File Name**: Enter File Name as “Consent Type_Approved_YEAR-MONTH-DAY.”
   Example: “Main consent_approved 2016-NOV-30”. If there is not an approval date of the consent, enter the name of the consent and the version number.
4. **Signed consent form**: Choose File to select the scanned consent form for upload.
5. **Consent Notes**: Enter consenting notes for participant. The consent notes should be specific to the consent process. This should be the same as the template consent notes and include important details related to the consent process.
6. Click “OK” if you are done uploading consents. Click “OK and Add Another” to add multiple consents.
IV. **Schedule Screening Visit(s).**

The participant now shows as "Consented" and the screening visit(s) will show under Visits.

a. Click “Schedule Visit” to schedule the screening visit.

b. The “Create Visit” pop-up will appear. Select Visit Date/Time and hit “OK.”
V. **Log Screening Visit Complete.**
   a. Click “Log Visit Complete.”

b. The Procedure Information page will open.
1. **Actual Visit Date:** This date and time auto-populate from the scheduled date and time of the visit. It is not editable on this page.

2. **Study Coordinator:** The study coordinator will default, you can change it from the drop-down.

3. **Was the participant compensated?** Select yes or no depending on if a participant stipend was paid for this visit.

4. **Visit Notes:** Add Visit Notes as appropriate.

5. **Is this visit complete?** Mark yes, if everything was completed and is correct. Please note that you are unable to edit visits that are marked complete. If all information is not completed and correct, mark no, so that you can go back in through “Log Visit Complete” and complete it.

6. **Participant Outcome:** Mark the participant outcome.

7. **Eligibility by waiver/not eligible comments:**

8. **Eligibility Waiver:**
   a. Click Finish.
VI. **Register Participant.**

The participant now shows as "Eligible" and can be registered to the study.

a. Click Register Participant on the left-hand side.

b. The "Register Participant" pop-up will appear. Complete the Registration Date, Arm, Treatment Start Date, Cohort, and Randomized Participant ID fields and click OK.

c. The participant will now show as “On Study” and the remaining study visits will populate.
VII. **Schedule and Log Study Visits.**
Now you will be able to continue to schedule and log study visits in the same manner as the screening visit.

VIII. **Record Electronic Data Capture (EDC) Entry Date.**
When you have recorded a participant’s information in the Sponsor’s EDC System, you will now record the date of capture in Click® CTMS.

a. From the Participant Summary page, click on the Visit Name. This will take you to the Visit Summary.

b. Click on Record Date to EDC under **Next Steps.** A pop-up will appear for the entry date for that visit.
### Completing the Visit Procedure Grid

The procedures associated with each visit in the protocol are captured in each visit’s procedure grid. The user will be able to update any procedures performed at the visit and capture any notes that pertain to each of the procedures. The system automatically assumes each procedure will be done and completed on the scheduled visit date. The user must go through the procedure list and update dates performed and indicate if procedures were not performed. A note is required for any procedure that has the amount changed to “0,” which indicated the procedure was not performed.

![Procedure Information](image)

**Procedure Information**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Sponsor</th>
<th>Optional</th>
<th>Billing Indicator</th>
<th>Amount</th>
<th>Date Performed</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-STS</td>
<td>Avanir Pharmaceuticals</td>
<td></td>
<td>RES</td>
<td>Units</td>
<td>11/2/2014</td>
<td></td>
</tr>
<tr>
<td>Chemistry, hematology, urinalysis</td>
<td>Avanir Pharmaceuticals</td>
<td></td>
<td>RES</td>
<td>Units</td>
<td>11/2/2014</td>
<td></td>
</tr>
<tr>
<td>Urine pregnancy test</td>
<td>Avanir Pharmaceuticals</td>
<td></td>
<td>RES</td>
<td>Units</td>
<td>11/2/2014</td>
<td>N/A Participant is male</td>
</tr>
<tr>
<td>Screening - Pt moving on to Baseline Visit (Finance Invoice for Entire Screening amount)</td>
<td>Avanir Pharmaceuticals</td>
<td></td>
<td>RES</td>
<td>Units</td>
<td>11/2/2014</td>
<td></td>
</tr>
<tr>
<td>Screening - Pt a Screen Failure - CRC add Comment listing all procedures performed during Screening Visits (Finance only)</td>
<td></td>
<td></td>
<td>RES</td>
<td>Units</td>
<td>11/2/2014</td>
<td></td>
</tr>
</tbody>
</table>
Other Participant Functions

I. **Edit Participant.**
   This action allows the user to edit the participant record.
   a. Click “Edit Participant” on the left-hand side.
      
      ![Edit Participant]

   b. This will take the user back into the participant record, where the user will be able to update parts of the demographics and participant data.
II. **Print Participant Record.**  
This action allows the user to print the participant record.

![Print Participant Record]

III. **Calendar View.**  
This action allows the user to view a calendar with the participant’s scheduled, completed, and projected visit dates.

![Calendar View]

**Next Steps**
- Update Registration
- Add Unplanned Visit
- Record Adverse Events
- Print Procedure Schedule
- Print Visit Slip
- Re-Consent
- Adjust Visit Dates
- Discontinue Per Protocol
- Export Visit Schedule
- Upload Additional Consent
- Log Public Comment
IV. **Update Registration.**
This action allows the user to update the participant’s registration date and treatment start date.

a. Click “Update Registration” under Next Steps.

b. The Update Registration pop-up will appear. The user can update the registration and treatment start dates for the participant here.

V. **Add Unplanned Visit.**
This action allows the user to create a new, unplanned visit for the participant.
VI. **Record Adverse Events.**
This action allows the user to add an adverse experience for the participant.

VII. **Print Procedure Schedule.**
This action allows the user to generate an excel document that contains the procedure visit association.

a. Click “Print Procedure Schedule” under **Next Steps.**

   ![Image of Next Steps](Image)

b. The Print Procedure Schedule pop-up will appear. The user can place a comment or an attachment that will be viewable in the participant’s history tab. Click “OK” to export the participant’s procedure schedule.

   ![Image of Print Procedure Schedule](Image)
c. The exported procedure schedule will be available in the participant’s history tab. Click on History.

![Procedure Calendar](image)

d. Click on the attachment under the activity, denoted with a paper clip icon. The excel formatted calendar will download to the user’s computer.

![Excel Calendar](image)

e. The procedure calendar will look similar to the sample below:

<table>
<thead>
<tr>
<th>Visit</th>
<th>Screening</th>
<th>Screening MRI Visit</th>
<th>Baseline</th>
<th>Phone Call Baseline LP</th>
<th>Month 1 (Visit 2)</th>
<th>Month 2 (Visit 3)</th>
<th>Month 3 (Visit 4)</th>
<th>Month 4 (Visit 5)</th>
<th>Month 5 (Visit 6)</th>
<th>Month 6 (Visit 7)</th>
<th>Month 7 (Visit 8)</th>
<th>Month 8 (Visit 9)</th>
<th>Month 9 (Visit 10)</th>
<th>Month 10 (Visit 11)</th>
<th>Month 11 (Visit 12)</th>
<th>Month 12 (Visit 13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1 - Screening 1</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Visit 2 - Baseline</td>
<td>X</td>
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<tr>
<td>Visit 3 - Month 3</td>
<td>X</td>
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<tr>
<td>Visit 4 - Month 6</td>
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<td>Visit 6 - Month 12</td>
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<tr>
<td>Visit 7 - Month 15</td>
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<tr>
<td>Visit 8 - Month 18</td>
<td>X</td>
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<tr>
<td>MRI</td>
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<tr>
<td>LP - Lumbar Puncture</td>
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<tr>
<td>LP with Fluoroscopy</td>
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<tr>
<td>LP Spine Films</td>
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<tr>
<td>Blood Patch</td>
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<tr>
<td>Phone Call</td>
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<tr>
<td>Recruitment and Retention (ALWAYS MARK COMPLETE)</td>
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<td></td>
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<td></td>
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</tr>
</tbody>
</table>

VIII. Print Visit Slip.
This action allows the user to generate an Excel document for the participant’s completed visits.

a. Click “Print Visit Slip” under Next Steps.
b. The Print Visit Slip pop-up will appear. Choose if the procedure information for each visit should be included.

c. The exported visit slip will be available in the participant’s history tab. Click on History.
d. Click on the attachment under the activity, denoted with a paper clip icon. The excel formatted visit slip will download to the user’s computer.

IX. **Re-Consent.**
This action allows the user to enter a re-consent for the participant. This action is used any time a consent form is revised and the new consent needs to be uploaded.

a. Click on “Re-Consent” under **Next Steps.**

b. The Re-Consent pop-up will appear. Click “Add” to re-consent the participant and add new consent information.
c. The Re-consent Forms pop-up will appear to add in the re-consent date, consent type, uploaded consent and consent notes.
1. **Re-Consent Date:** Enter date of re-consent.
2. **Select Consent Type and Name:** Select consent type from the drop-down menu.
3. **File Name:** Enter File Name as “Consent Type_Approved_YEAR-MONTH-DAY.”
   Example: “Main consent_approved 2016-NOV-30”. If there is not an approval date of the consent, enter the name of the consent and the version number.
4. **Signed consent form:** Choose File to select the scanned consent form for upload.
5. **Consent Notes:** Enter consenting notes for participant. The consent notes should be specific to the consent process. This should be the same as the template consent notes and include important details related to the consent process.
   - Click “OK” if you are done uploading consents. Click “OK and Add Another” to add multiple consents.

**X. Adjust Visit Dates.**
This action allows the user to adjust the target date(s) for the study visits.
   - Click “Adjust Visit Dates” under **Next Steps.**

---

**XI. Discontinue Per Protocol.**
This action allows the user to discontinue the participant from the study protocol. This is not the action that will be used for a screen failure.
a. Click “Discontinue Per Protocol” under **Next Steps**.

XII. **Export Visit Schedule.**
This action allows the user to export the schedule for the participant.

a. Click “Export Visit Schedule” under **Next Steps**.

XIII. **Upload Additional Consent.**
This action allows the user to upload documents for additional consent forms. This action is used for any sub-study consents, or additional consents for the study.
XIV. **Log Public Comment for Participant.**
This action allows the user to log a communication at the participant level. You can also attach documents to the participant’s file.

a. Click “Log Public Comment” under **Next Steps.**
The “Log Public Comment” pop-up will appear.

b. Enter comment and attach documentation (if necessary) and click “OK” to save.
Study Functions

I. **View Project.**  
This action allows the user to view the project workspace.

II. **Print Project.**  
This action allows the user to print the project workspace.

III. **Add Participant.**  
This action allows the user to add a new participant to the study. See [Add Participant to Study](#) for more information.

IV. **Record Monitored Visits/CRF Submission.**  
This action allows the user to record monitor visit and CRF submission dates. Banner Research is not using this feature.

V. **Calendar View.**  
This action allows the user to view a calendar with all study participants' scheduled, completed, and projected visit dates.

VI. **Log Event or Milestone.**  
This action allows the user to log and capture revenue that happens at a study level, or items that aren't captured on a per-visit basis. Examples include: Study Start-Up costs, Rater Training, Monitoring Visits, Travel, etc.

   a. Click Log Event or Milestone under **Next Steps.**
b. The Log Event or Milestone pop-up will appear.

1. **Event or Milestone Date** field is where you will enter the date the Event or Milestone occurred. This could be the start date of the study for Study Start-up costs, the date of training for Rater Training, the yearly anniversary of the study start date for renewals on costs for the Pharmacy or Imaging Center, etc.

2. **Associated Sponsor** field is not required, but the drop down will contain the study sponsor(s) to choose from.

3. In the **Event or Milestone Description**, you will input as much detail about the invoiceable line item as possible. The easiest way to do this is to copy/paste it from the Huron Export you receive after the Budget Implementation Meeting.

<table>
<thead>
<tr>
<th>INVOICEABLE</th>
<th>AMOUNT</th>
<th>NOTES</th>
<th>BILLING NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Start-Up</td>
<td>$5,000.00</td>
<td>A non-refundable study set up payment of $5,000 for Clinical Study set up related activities including, but not limited to, completion of regulatory documents, review of the Protocol, and Investigator's Brochure, and training on Clinical Study related activities will be made upon execution of the Agreement, confirmation of RME meeting and approval of an initiation fee, and receipt of &quot;Approval to Screen and Fundraising&quot;. Study Coordinator will need to enter as Log Event or Milestone in Huron InKnowlogy Finance of this event for billing.</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Start-Up</td>
<td>$2,000.00</td>
<td>Pharmacy set ups will be invoiced by the Institution to Huron and will include the Pharmacy's review of drug approval information, as well as any site specific set up fees required for study. The minimum reimbursement for these fees is $2,000.</td>
<td></td>
</tr>
<tr>
<td>Expected Site Activation Payment</td>
<td>$5,000.00</td>
<td>If Huron does not receive a subject within 30 days of receipt of the Approval to Screen and Fundraising notice, an additional, one-time, non-refundable payment of $5,000 will be made. Study Coordinator will need to enter as Log Event or Milestone in Huron InKnowlogy Finance of this event for billing.</td>
<td></td>
</tr>
<tr>
<td>Local PIEEs</td>
<td>$4,000.00</td>
<td>Local PIEEs to cover the initiation, amendments, and continuing fees will be submitted by the Institution to Huron and will be reimbursed directly to the Institution upon receipt of invoice. The maximum reimbursement for PIEEs is estimated to be $4,000. Study Coordinator will need to enter as Log Event or Milestone in Huron InKnowlogy Finance of this event for billing.</td>
<td></td>
</tr>
<tr>
<td>Recruitment Funds</td>
<td>$5,000.00</td>
<td>In accordance to the site, Recruitment also includes a maximum of $5,000 for the site name in Subject recruitment and Subject Chart Review. All recruitment activities must be approved by Huron in advance of scheduling in order to be eligible for reimbursement. Any additional funds that may be approved in advance by Huron.</td>
<td></td>
</tr>
<tr>
<td>Supplemental Protocol Fee</td>
<td>$3,000.00</td>
<td>Includes clinical assessments, safety evaluations, safety evaluations to further assess adverse events, and ECRs performed in addition to those set forth in the Protocol. Maximum reimbursement is $3,000. The supplemental protocol procedures will be reimbursed up to the contract negotiated rates set forth in Schedule 6. Study Coordinator will need to enter as Log Event or Milestone in Huron InKnowlogy Finance of this event for billing.</td>
<td></td>
</tr>
</tbody>
</table>

4. **Attach Documents** is where any documentation that needs to be included would be attached. This includes receipts for travel and meals, mileage logs, rater training logs, etc.
VII. **Log Public Comment.**

This action allows the user to log a communication at the study level. You can also attach documents.

a. Click Log Public Comment under **Next Steps.**

b. The Log Public Comment pop-up will appear. Enter comment for study and hit “OK.”